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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,581

02/08/2006

Dan Hashimshony

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03/17/2010

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EXAMINER

FERNANDEZ, KATHERINE L

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

03/17/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/567,581	<b>Applicant(s)</b> HASHIMSHONY, DAN	
	<b>Examiner</b> KATHERINE L. FERNANDEZ	<b>Art Unit</b> 3768	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-60 and 62-91 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-60 and 62-91 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 March 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: ____.                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date  
:11/29/07;7/17/08;12/28/08;2/1/09;6/11/09;7/26/09;1/8/10

***Claim Objections***

1. Claims 1,21,53 and 69 are objected to because of the following informalities:

In claim 1, in line 2, "intracorporeal portions" should be made singular in order to be consistent with the dependent claims. A similar objection is made for claim 21, line 4 and claim 69, line 4.

Claim 53 is currently disclosed as dependent on itself. Examiner assumes that Applicant intended claim 53 to be dependent on claim 58.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-60 and 62-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Although the specification disclose an electromagnetic sensor for tissue characterization (see original specification, filed 2/8/2006, pg. 3, lines 12-14), there is no disclosure that the electromagnetic sensor is operative in an electromagnetic frequency range of less than 100 GHz or less than 10 GHz. Therefore, the added limitations disclosing that the electromagnetic sensor is operative in an electromagnetic frequency range of less than 100 GHz or less than 10

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GHz (see claims 81 and 85) are considered to be new matter. With regards to the Remarks filed by Applicant on April 8, 2008, Examiner disagrees with Applicant's argument that the new limitations concerning the electromagnetic frequency range are supported by the specification as the claimed frequency range includes a specific range from a disclosure of a broad range, wherein the specific range is not disclosed in the specification.

4. Claims 1-60 and 62-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Although the specification disclose an electromagnetic sensor for tissue characterization (see Specification filed 3/14/2008, pg. 3, lines 12-14), there is no disclosure that the electromagnetic sensor is operative in an electromagnetic frequency range of less than 100 GHz or less than 10 GHz.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-4,6-8, 10-11,13-24,30-31,33-34,36-40,42-43,69-78,80-82,84-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iddan (US Patent No. 6,936,003) in view of King et al. (US Patent No. 5,227,730).

Iddan discloses an endoscope and a method for tissue characterization using the endoscope, which comprises: an intracorporeal portion, configured for insertion into a body, and including: a nonirradiative electromagnetic sensor for tissue characterization (column 3, lines 28-51; column 3, line 62-column 4, line 25); a communication line, on which the electromagnetic sensor is mounted (column 4, lines 39-59, see Figure 1A); an extracorporeal portion, configured for manipulating the intracorporeal portion (column 3, lines 18-27; column 5, lines 6-19); and a control station (column 5, lines 21-62). With regards to claims 2 and 22, the communication line is formed as an instrument bundle (column 4, lines 39-59; see Figure 1A). With regards to claims 3 and 23, the instrument bundle extends beyond a distal-most end of the endoscope, with respect to an operator (column 3, line 18-51; column 3, line 62-column 4, line 25; see Figure 1A) , and a distal-most end of the instrument bundle may be manipulated, extracorporeally, to bring the electromagnetic sensor to contact with tissue, for characterization (column 5, lines 6-19, lines 36-62). With regards to claim 4, the intracorporeal portion further includes an instrument channel, and the electromagnetic sensor for tissue characterization is inserted into the instrument channel (column 4, lines 39-59; see Figure 1A). With regards to claims 6, 24, 30 and 86, the endoscope further includes a catheter, wherein the electromagnetic sensor is inserted into the catheter, and the catheter is inserted into the instrument channel (column 3, lines column 3, lines 28-51; column 3, line 62-column 4, line 25; column 4, lines 39-59; see Figure 1A). With regards to claims 7, 31 and 87, the catheter extends beyond a distal-most end of the endoscope, with respect to an operator, and a distal-most end of the catheter may be manipulated independently of

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the distal-most end of the endoscope (column 3, lines 28-51; column 3, line 62-column 4, line 25; column 4, lines 39-59; see Figure 1A). With regards to claim 8, the intracorporeal portion further includes an optical channel for an optical instrument (column 3, lines 28-51; column 3, line 62-column 4, line 25; column 4, lines 39-67; see Figure 1A). With regards to claims 10-11 and 33-34, the intracorporeal portion further includes a second instrument (i.e. optical sensor, temperature sensor, impedance sensor, etc.) (column 3, line 28-column 4, line 25; see Figure 1A). With regards to claims 13, 17, 36, 40 the intracorporeal portion is designed for motion in a body lumen (i.e. a gastrointestinal tract, a colon, a vagina, a uterus, a blood vessel, etc.) (column 3, lines 1-6; column 5, lines 6-19, 36-62). With regards to claims 14 and 38-39, the intracorporeal portion is designed for reaching the lumen by percutaneous insertion (column 3, lines 1-6). With regards to claim 15, the endoscope is configured for characterizing a tissue along the lumen wall (column 14, lines 49-55). With regards to claims 16 and 37, the endoscope is configured for characterizing a tissue outside the lumen, by penetrating the lumen wall (column 3, line 62-column 4, line 25; column 14, lines 38-55; column 3, lines 1-6). With regards to claim 70, the control station further includes at least one of a control unit, control buttons, a keyboard, a read/write device, a signal analyzer, and a display screen (column 5, lines 21-62). With regards to claims 72-74, the second instrument is configured for taking a biopsy sample, localized surgery, and dispensing medication (column 3, lines 28-51; column 3, line 62-column 4, line 25). With regards to claims 75-77, the intracorporeal portion includes a cutting tool (column 3, lines 28-51; column 3, line 62-column 4, line 25). With regards to claims 88-

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91, the distal-most end of the catheter is manipulated electronically and manually (column 5, lines 6-62).

However, although Iddan discloses that the sensors used in their device can include a variety of sensors used for tissue characterization, such as a sensor for determining electrical impedance of tissues and an electromagnetic sensor (column 3, lines 28-51), they do not specifically disclose that the electromagnetic sensor is operative in an electromagnetic frequency range of less than 100 GHz. With regards to claim 81 and 85, they do not specifically disclose that the electromagnetic sensor is operative in an electromagnetic frequency range of less than 10 GHz. Further, with regards to claims 19-20 and 42-43, they do not specifically disclose that the tissue characterization relates to the detection of malignancy or to the detection of a pre-cancerous state. Further, with regards to claims 80 and 84, Iddan does not specifically disclose that the electromagnetic sensor includes a resonating element, formed as a conductive structure, configured to be placed proximally to an edge of the tissue, without penetrating the tissue, and having a diameter-equivalent  $D$ , which defines a cross-sectional area of the resonating element, on a plane substantially parallel with the edge of the tissue; and at least one conductive lead, for providing communication with an external system, wherein the resonating element is configured to resonate at a free-air wavelength range of between about  $\lambda$  and about  $10\lambda$ , wherein  $\lambda$  is at least about ten times the diameter-equivalent  $D$ , and wherein upon receiving a signal in the range of between about  $\lambda$  and about  $10\lambda$ , the electromagnetic sensor is configured to induce electric and magnetic fields, in a near zone, in the tissue, the near zone being a



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hemisphere having a diameter of substantially  $D$ , beginning with the edge of the tissue, while causing negligible radiation in a far zone, so that the tissue, in the near zone, effectively functions as part of the resonating element, and wherein different tissue types have different resonating responses to the electromagnetic sensor, so that the tissue, in the near zone, may be categorized, by the resonating response to the nonirradiative electromagnetic sensor.

King et al. disclose a method and apparatus for in vivo or in vitro sensing of complex dielectric properties of lossy dielectric materials, particularly biological tissue (column 1, lines 6-9). Their invention provides a needle-like microwave resonator sensor which can be inserted into a penetrable dielectric material for the purpose of measuring or monitoring the dielectric properties of the material and thus distinguish between different types of biological tissue, such as between tumors and normal tissue (column 2, lines 41-55; column 1, lines 32-61; column 3, line 38-column 4, line 54).

Note that it is well known in the art that the electromagnetic frequency range of microwaves is less than 100 GHz and less than 10 GHz. They disclose that their sensor is exceptionally sensitive to small variations (column 2, lines 41-55). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Iddan to include an electromagnetic sensor, with the above limitations of claims 80 and 84, operative in an electromagnetic frequency range of less than 100 GHz and have the tissue characterization relate to the detection of malignancy or of a pre-cancerous state, as Iddan requires a sensor that characterizes tissue and King

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teaches such a sensor that is exceptionally sensitive to small variations and able to differentiate between malignant and normal tissue (column 2, lines 41-55).

7. Claim 5,25-29,44-60 and 62-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iddan in view of King et al. as applied to claims 4 and 24 above, and further in view of Ouchi (US Patent No. 6,203,533).

As discussed above, the above combined references meet the limitations of claim 4 and most of the limitations of claims 44-45,51-60 and 62. Further, with regards to claims 25-29,44,46-51,53-58 and 63-68, Iddan discloses that their method further includes a second instrument inserted in the endoscope and performing a second procedure with the second instrument, wherein the second procedure includes taking a biopsy sample, a localized surgery, dispensing medication, and characterizing the tissue by an additional sensor (column 3, line 28-column 4, line 25).

However, they do not specifically disclose that the electromagnetic sensor for tissue characterization may be removed from the instrument channel and replaced with the second instrument. Further, they do not specifically disclose inserting a guide wire to the location of the characterized tissue and inserting the second instrument into the instrument channel along the guidewire. Ouchi discloses an injector instrument, for insertion into a forceps channel of an endoscope, which is inexpensive, is easily fed around bends in a forceps channel, is sufficiently small to be inserted into even a thin forceps channel and is easily cleansed and disinfected (column 4, lines 26-30, 58-67). The injector instrument is removably inserted through a forceps channel of an endoscope (column 10, lines 11-16; column 14, lines 1-3). A guide tube can be inserted

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in the forceps channel of the endoscope and the injector instrument inserted along the guide tube (column 20, lines 21-27). They further disclose that other treatment accessory devices can be inserted in the forceps channel and by doing so the size of the endoscope is not increased (column 23, lines 23-30; column 24, lines 26-45; column 29, lines 31-39). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of the above combined references to have the electromagnetic sensor be removed from the instrument channel and replaced with the second instrument and insert the second instrument into the instrument channel along an inserted guide wire, as taught by Ouchi, in order to be able to effectively clean and disinfect the electromagnetic sensor, be able to use a variety of instruments without increasing the size of the endoscope and properly position the second instrument (column 4, lines 26-30, 58-67; column 29, lines 31-39).

8. Claims 9, 12, 32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iddan in view of King et al. as applied to claims 9, 10, 21 and 33 above, and further in view of Nevo et al. (US Pub No. 2003/0187347).

As discussed above, the above combined references meet the limitations of claims 9, 10, 21 and 33. Iddan further disclose that their method includes inserting an optical instrument (column 3, lines 28-51). However, they do not specifically disclose that the second instrument, such as an optical instrument, is configured to sense/visually observe the electromagnetic sensor as it makes contact with a tissue. Nevo et al. discloses that their invention includes the use of a separate set of tracking coils for tracking purposes (i.e. electromagnetic sensor), and a separate set of imaging

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coils for imaging purposes (i.e. MR sensor) (pg. 6, paragraph [0076], pg.3, paragraph [0029]). The control system controls the set of tracking coils to sense and indicate the location and orientation of the probe within the body cavity and controls the set of imaging coils to image selective areas within the body cavity (pg. 3, paragraphs [0028]-[0029]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of the above combined references to have the second instrument be configured to sense/image the electromagnetic sensor, as taught by Nevo et al., in order to enable the instrument to characterize selected areas within the body cavity (pg.3, paragraph [0028]-[0029]).

9. Claims 79 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iddan in view of King et al. as applied to claim 78 above, and further in view of Hashimshony (US Pub No. 2003/0187366).

As discussed above, the above combined references meet the limitations of claim 78. However, they do not specifically disclose that the nonirradiative electromagnetic sensor is configured for: applying an electrical pulse to the tissue; generating an electrical fringe field in a near-field zone of the tissue, so as to produce a reflected pulse from the near-field zone of the tissue with negligible radiation penetrating the tissue; and detecting the reflected electrical pulse. Hashimshony disclose a method and apparatus for examining tissue in order to differentiate the examined tissue from other tissue (i.e. differentiate between cancerous and normal, healthy tissue) according to the dielectric properties of the examined tissue (pg. 1, paragraph [0001]). They disclose that their apparatus comprises of applying an electrical pulse to the tissue to be

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examined via a probe such that the probe generates an electrical fringe field in the examined tissue and produces a reflected pulse therefrom, with negligible radiation penetrating into other tissues or biological bodies near the examined tissue; detecting the reflected electrical pulse; and comparing electrical characteristics of the reflected electrical pulse with respect to the applied electrical pulse to provide an indication of the dielectric properties of the examined tissue (pg. 2, paragraphs [0017]-[0018]; pg. 5, paragraph [0059]; see Figures 4 and 6). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the sensor taught by Hashimshony substitute for the electromagnetic sensor of the above combined references, as the above combined references require a sensor that can differentiate between different types of tissue and Hashimshony teaches such a sensor.

### ***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE L. FERNANDEZ whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/  
Primary Examiner, Art Unit 3768